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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Greasley, Peter

Serial No: 10/521,420

Filed: January 14, 2005

For: METHODS TO IDENTIFY TRUE
ANTAGONISTS AND INVERSE
AGONISTS OF THE
CANNABINOID RECEPTOR

Attorney Docket No.: ASZD-P01-752

Art Unit: 1649

Examiner: ULM, John D.

Confirmation No.: 9948

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

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REPLY TO RESTRICTION REQUIREMENT

Sir:

This amendment is being filed in reply to the outstanding Restriction Requirement, mailed October 24, 2005, in connection with the above application. Applicant notes that the Office has restricted the pending claims to Group I, claims 1-10 and 17-31, and Group II, claims 11-12 and 15-16. Applicant hereby provisionally elects Group I *with traverse*. Applicant's traversal is for the reasons that follow.

The Office submits that Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: "The receptor protein of group I and the compound of group II are structurally unrelated and, therefore, do not share a common feature or combination of features that distinguishes them as a group from the prior art." Applicant

disagrees and notes that the Office has placed special emphasis on the structural relation of the receptor protein of Group I and the compound of Group II. Applicant asserts that the structural relationship between the compound of Group II and the *protein* of Group I is inapposite to the determination of unity of invention in the present case. Rather, the relationship between the compounds of Group II and the *compounds* identified by the methods of Group I is material, and it is clear that these compounds are one and the same.

Applicant contends that the identity, and hence, the structural features of the compounds of Group II are indeed what is discovered by the methods of Group I. As such, both Groups I and II share the same or corresponding special technical features and possess unity of invention. That is to say, the compounds of Group II and the methods of Group I are linked as product and method of making/identifying said product, respectively. PCT unity of invention practice instructs that independent claims to a product and a method for making said product are to be examined together. For example, MPEP 1850 under the section “A. Combinations of Different Categories of Claims” states:

The method for determining unity of invention under PCT Rule 13 shall be construed as permitting in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product...

(see also 37 CFR 1.475(b)(1), which restates the above passage from MPEP 1850). The Office has not provided any indication to dispute the above satisfied PCT criteria supporting unity of invention. As such, Applicant asserts that the present holding of lack of unity is improper and requests reconsideration.

The Office does, however, provide the conclusory statement that the shared special technical features of Groups I and II do not “distinguish them as a group from the prior art,” yet no evidence or even rationale is provided to support this assertion. Thus, since the compounds of Group II are produced/identified through the methods of Group I, it is evident that Groups I and II possess unity of invention *a priori*. Yet the Office presumes that there is a lack of invention *a posteriori* without having presented any art of record. Applicant submits that in order for lack of unity to be found, the Office must introduce art to support its position (MPEP 1850 -

“DETERMINATION OF “UNITY OF INVENTION”). Otherwise, the finding of lack of unity for the claims of Groups I and II is untenable.

Applicant highlights that the claims of Group II depend from those of Group I. As such, according to MPEP 1850:

If independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend of the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention...

Thus, the claims of Group II should be rejoined with the claims from Group I from which they depend. According to MPEP 809.03 and US restriction practice, claim 1 is a linking claim: “(B) a claim to the necessary process of making a product linking proper process and product claims...” As such, on allowance of the linking claim, pursuant to MPEP 809: “Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.” Thus, even if the restriction were to be made final, on indication of allowance of linking claim 1, Applicant notes that dependent claims 11-12 and 15-16 (Group II) must be rejoined and fully examined; that is, when a generic/linking claim is found allowable, “applicant must be advised of the allowable generic claim and that claims drawn to the nonelected species are no longer withdrawn since they are fully embraced by the allowed generic claim” (MPEP 809.02(c)). Accordingly, both PCT unity of invention practice and US restriction practice specify that the claims of Group II must be rejoined with those of Group I at least on allowance of claim 1.

Lastly and most importantly, Applicant respectfully highlights that pursuant to MPEP 1850, “it is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority.” Furthermore, the Office is kindly directed to Article 27(1) PCT, which states that:

No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

Applicant respectfully point out that in the instant case *neither* the International Searching Authority *nor* the International Preliminary Examining Authority found lack of unity of invention in either the International Search Report or the International Preliminary Examination


Report. The apparent disregard for both the ISA's and the IPEA's finding of unity of invention under 37 CFR 1.475 evinces the impropriety of the instant restriction requirement.

For the above reasons, Applicant requests that the claims of Groups I and II be rejoined and examined in their entirety.

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicant hereby petitions for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,

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